

### REMARKS

This Amendment is submitted in reply to the final Office action mailed on March 25, 2010. The Office Action provided a three-month shortened statutory period in which to respond, ending on June 25, 2010. Accordingly, this Amendment is timely submitted. No fees are believed due with this Amendment. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 50-4498 in the name of Nestle Nutrition.

Claims 1-3 and 5-11 are currently pending. Claim 3 was previously cancelled without prejudice or disclaimer. In the Office Action, Claims 1-11 are rejected under 35 U.S.C. §103. Applicant does not acquiesce in the correctness of the rejections or objections and reserves the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

In response, Claim 1 has been amended and Claims 6-7 have been cancelled without prejudice or disclaimer. These amendments do not add new matter and are supported in the specification at, for example, page 4, line 37-page 5, line 8. In view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that the rejections should be reconsidered and withdrawn.

In the Office Action, Claims 1-3 and 5-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 7,374,753 to Farmer et al. ("*Farmer*") in view of the combination of U.S. Publication No. 2005/0244392 to Pei et al. ("*Pei*") and "Enterotoxin-binding glycoproteins in a Protease-Peptone Fraction of Heated Bovine Milk" to Shida et al. ("*Shida*") and in view of U.S. Publication No. 2004/0052895 to Ivey et al ("*Ivey*") and further in view of "Preparation and Properties of Shiga Toxin and Toxoid" to Dubos et al. ("*Dubos*"). Applicant respectfully submits that the cited references are deficient with respect to the present claims.

Currently amended independent Claim 1 recites, in part, a method for treating the effects of infection by enterotoxin-producing pathogens comprising administering to a human or animal in need of same an oral composition comprising from about 0.3% to about 7% by volume of peptones and about 0.3% to about 7% by volume of meat extract. The amendment does not add

new matter and is supported in the specification at, for example, page 4, line 37-page 5, line 8. Applicant has surprisingly found that by ingesting meat extracts together or not with peptones, or peptones alone, individuals suffering from infection by pathogens as evidenced by intestinal disorders such as, for example, failure of gut epithelial integrity and diarrhea, have a normalized fluid secretion, a cellular structure less damaged, and a decreased inflammation compared to individuals having the same disorders, but a diet not supplemented with meat extracts or peptones. See, specification, page 5, lines 20-25. Applicant respectfully submits that the cited references fail to disclose or suggest each and every element of the present claims.

For example, *Farmer, Pei, Shida, Ivey and Dubos* fail to disclose or suggest methods for treating the effects of infection by enterotoxin-producing pathogens comprising administering to a human or animal in need of same an oral composition comprising from about 0.3% to about 7% by volume of peptones and about 0.3% to about 7% by volume of meat extract, as required, in part, by the present claims. Instead, *Farmer* is entirely directed to the use of compositions including a lactic acid bacteria for administration to the intestinal tract for inhibiting infections including Sudden Infant Death Syndrome (“SIDS”). At no place in the disclosure does *Farmer* consider the use of compositions having peptones and meat extracts, let alone compositions having peptones and meat extracts in the presently claimed volumetric amounts.

The Patent Office asserts that “[p]eptones and meat extract are used in a culture for B. coagulans Hammer bacteria which is used in the inhibition of the pathogenic bacteria shown supra (example 1).” The Patent Office further states that “the use of both peptones and meat extract in example 1 read on instant claim 1 because the claim recites that the two ingredients are used **in the manufacture** of an oral composition.” See, Office Action, page 3, line 24-page 4, line 4 (emphasis in original). However, Applicant directs the Patent Office to the language of Claim 1, which was previously amended to delete the phrase “[u]se of peptones and/or meat extract in the manufacture of an oral composition.” Instead, Claim 1 requires administration to a human or animal in need of treatment for the effects of infection by enterotoxin-producing pathogen a composition having from about 0.3% to about 7% by volume of peptones and about 0.3% to about 7% by volume of meat extract. Since the peptones and meat extract of *Farmer* are only used as a culture medium to grow bacteria and never in a composition administered to a human or an animal, and since *Farmer* fails to disclose the presently claimed volumetric

amounts of peptones and meat extract, Applicant respectfully submits that *Farmer* is deficient with respect to the present claims.

*Pei* is entirely directed to a process for the selection of new probiotic strains and the corresponding probiotic strains. See, *Pei*, Abstract. Indeed, the Patent Office cites *Pei* solely for the disclosure of probiotic compositions. See, Office Action, page 4, lines 13-18. However, at no place in the disclosure does *Pei* consider the use of compositions having peptones and meat extracts, let alone compositions having peptones and meat extracts in the presently claimed volumetric amounts.

*Shida* is entirely directed to the examination of binding of *Escherichia coli* heat-labile enterotoxin to milk proteins using Western blot technique. See, *Shida*, Introduction. Indeed, the Patent Office cites *Shida* solely for the disclosure of inhibiting or treating enterotoxin-producing bacteria. See, Office Action, page 5, lines 7-9. However, at no place in the disclosure does *Shida* consider the use of compositions having peptones and meat extracts, let alone compositions having peptones and meat extracts in the presently claimed volumetric amounts.

*Ivey* is entirely directed to a nutrient formulation including moisture, a coloring agent, a palatability modifier and/or an adjuvant that is designed for use in poultry and other animals, and a method of feeding it that improves subsequent livability, cumulative feed efficiency, weight gain, and resistance to disease challenge or other stresses. See, *Ivey*, Abstract. Indeed, the Patent Office cites *Ivey* solely for the disclosure of compositions having a specific amount of yeast. See, Office Action, page 5, lines 12-14. However, at no place in the disclosure does *Ivey* consider the use of compositions having peptones and meat extracts, let alone compositions having peptones and meat extracts in the presently claimed volumetric amounts.

*Dubos* is entirely directed to the preparation and properties of Shiga exoneurotoxin and the toxoid derived from same. See, *Dubos*, Abstract. Similar to *Farmer*, any use of peptones and/or meat extract in *Dubos* is solely as a culture medium to grow *Shigella dysenteriae*. See, *Dubos*, Abstract; Materials and Methods. The Patent Office asserts that since *Dubos* uses 500 g peptone and 125 g meat extract in 2500 ml of water, that *Dubos* teaches the presently claimed volumetric amounts of peptones and meat extract. See, Office Action, page 5, line 21-page 6, line 2. Applicant respectfully disagrees and submits that the Patent Office has excluded several additional components used to create the medium. For example, the concentrate is prepared

using 500 g peptone, 135 g meat extract and 2500 ml water. 50 ml of this concentrate is combined with 950 ml water, 10 g  $\text{Na}_2\text{HPO}_4$ , 1 ml of 50% NaOH, 10 ml of 10%  $\text{CaCl}_2$ , 2 g glucose, 1 g fumaric acid and 5 g Na pyrophosphate. See, *Dubos*, Materials and Methods. Applicant respectfully submits that it is improper for the Patent Office to select only portions of the recipe for the medium and use the portion as disclosure that the final composition includes a specific amount of peptones and meat extract. Thus, since any peptones and/or meat extract of *Dubos* are only used as a culture medium to grow bacteria and never in a composition administered to a human or an animal, and since *Dubos* fails to disclose the presently claimed volumetric amounts of peptones and meat extract, Applicant respectfully submits that *Dubos* is deficient with respect to the present claims.

For at least the reasons set forth above, Applicant submits that the cited references fail to disclose or suggest each and every element of the present claims. Thus, Applicant submits that Claims 1-3, 5 and 8-11 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Applicant respectfully requests that the rejection of Claims 1-3 and 5-11 under 35 U.S.C. §103 be reconsidered and withdrawn.

In the Office Action, Claims 1-3 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over Claims 1 and 5 of co-pending U.S. Serial No. 10/595,396. The Patent Office asserts that, although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications are drawn to similar oral compositions. See, Office Action, page 6, lines 19-21.

In response, Applicant submits that, at this stage in prosecution, it would be premature to file a terminal disclaimer because the instant claims have not yet been allowed, and thus, the final version of these claims is not yet known. Further, Applicant also submits that the claims of co-pending U.S. Serial No. 10/595,396 may also be amended to include subject matter not contained in the claims of the present application. At such time when the claims of any of the pending applications become allowed, Applicant will reassess the double patenting rejection in view of the allowed claims.

For the foregoing reasons, Applicant respectfully requests reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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